

Creating Bulk Ingredient Listing SPL Documents

Basic instructions for creating
technically valid Bulk Ingredient
Listing SPL Documents
Version 1.0

Use SPL Starter Package

- Link to SPL Starter Package is located under the heading "Resources" on this web page:
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

***You can also utilize other SPL authoring software solutions to create valid SPL documents. See this web page: <http://spl-work-group.wikispaces.com/Vendors>

NOTE: This is NOT an FDA endorsement for these software products.

Accessing the Listing SPL Xforms

- Open listing SPL document Xforms file “SPLForm_DrugListing.xhtml” (or equivalent in your SPL authoring software.)

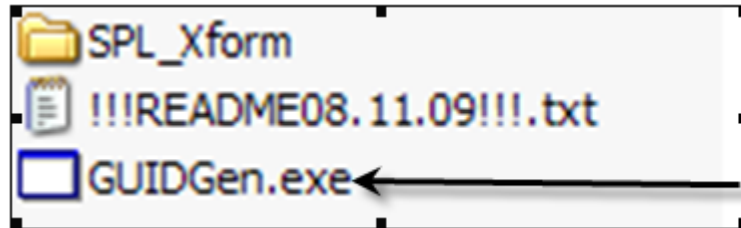
Selecting Document Type



The screenshot shows a software interface with a menu bar containing 'Open', 'Save As', and 'Save'. Below the menu bar are four tabs: 'Document Information', 'Drug Listing', 'Content of Labeling', and 'Preview'. The 'Document Information' tab is active, showing a section titled 'Document Information'. Within this section, there is a label 'Type of document' and a dropdown menu. The dropdown menu is open, displaying 'BULK INGREDIENT' as the selected option. A small blue arrow icon is visible at the end of the dropdown menu.

- Select “Bulk Ingredient” from the drop-down menu.

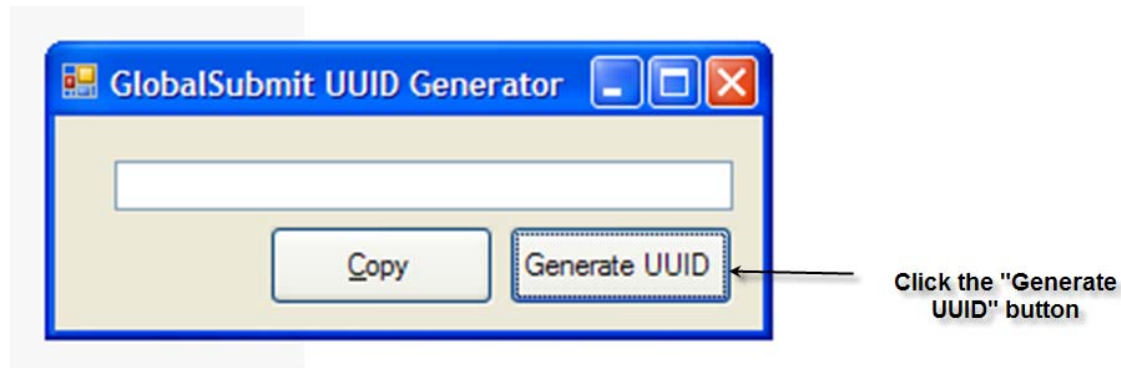
Generating GUIDs for IDs



Use the **GUID** generator executable file
or online version

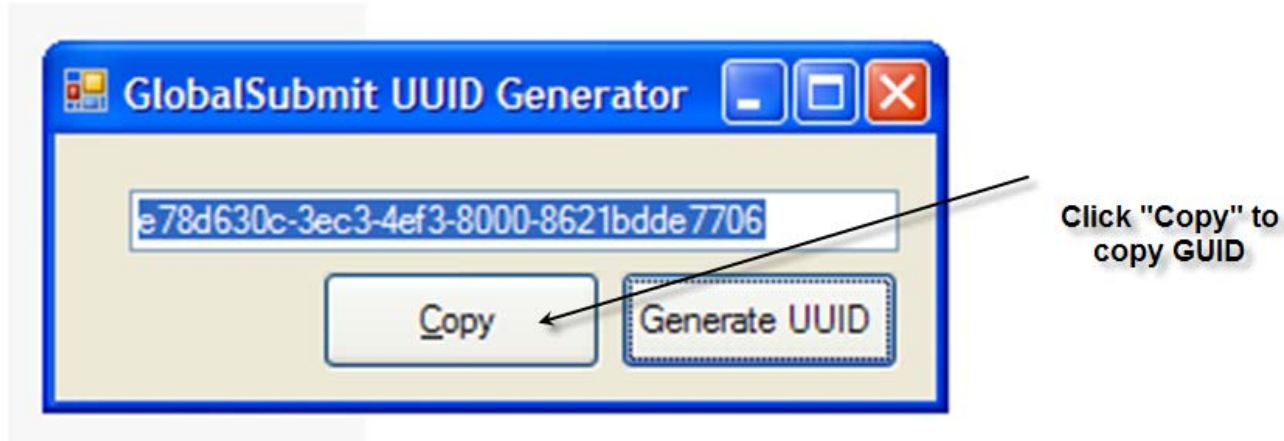
- Locate the Globally Unique Identifier (GUID) generator in the folder containing the SPL Xforms. GUIDs are also referred to as Universal Unique Identifiers (UUIDs)
- Double click executable file named “GUIDGen.exe.”
- If this program is incompatible with your PC, then search for an “online GUID generator” via your internet browser.

Generating GUIDs for IDs cont...



- Generate a GUID by choosing the “Generate UUID” button (or equivalent in online GUID generator tool.)

Generating GUIDs for IDs cont...



- Copy a GUID by choosing the “Copy” button (or equivalent in online GUID generator tool.)

Adding a SPL Document ID

ID

c46d775b-d995-4bc7-b3ac-e979c8c157aa

- Paste GUID in “ID” field
- The id root uniquely identifies a specific SPL file. Each new version of an SPL file has a new id root. The id root is a Globally Unique Identifier (GUID).
- Hereafter, the “id root” will be referred to as “ID” or “document ID” in this eBook.

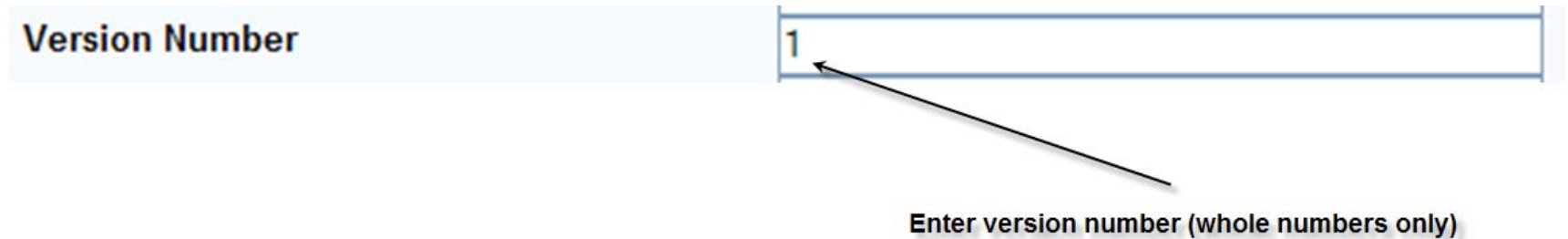
Assigning a Set ID

Set ID

c2ad48a4-85ca-47b7-bb66-f260802e8c88

- Generate and copy another GUID using the GUID generator.
- Paste this GUID in the “Set ID” field.
- The setID root uniquely identifies a group of versions of an SPL file.

Version Number



A form with a light blue header bar containing the text "Version Number". To the right of the header is a white input field with a blue border. The number "1" is entered in the input field. A black arrow points from the text "Enter version number (whole numbers only)" below to the input field.

Version Number

1

Enter version number (whole numbers only)

- Enter a version number.
- The version number must be a **whole** number greater than zero.
- No spaces should be included before or after the version number.

Entering a Document Date

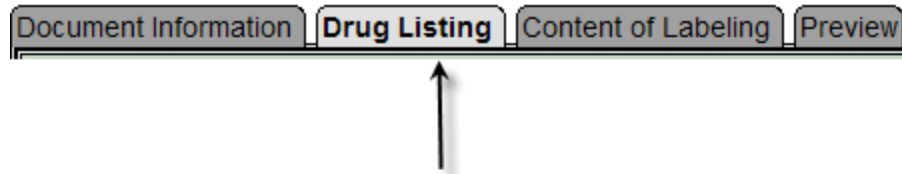
| | |
|----------------|----------|
| Effective Time | 20090920 |
|----------------|----------|

Enter approximate submission date



- Enter a document date (Effective Time)
- Ensure that there are no spaces (created w/keyboard space bar) before or after date.
- The effective time provides a date reference to the SPL version. The date includes the year, month and day using the format yyymmdd.

Navigating to the Drug Listing Screen



Click the "Drug Listing" tab

- Now that you have entered the document tracking information, navigate to the drug listing screen by clicking the "Drug Listing" tab.


Entering the Labeler's Name

| Labeler | |
|---------|--|
| Name | <input type="text" value="Acme APIs"/> |

- Type in the name of the labeler.
- The labeler is the registrant or private label distributor (PLD) requesting the NDC Labeler Code or the registrant or PLD who is submitting an already assigned NDC Labeler Code.
- Ensure that the labeler name is the same as the name in the NDC Labeler Code SPL that has the labeler code which is the first segment of the NDC in this listing SPL.

Labeler's DUNS Number

| Labeler | |
|-------------|-----------|
| Name | Acme APIs |
| DUNS Number | 752918231 |



Enter the DUNS Number for the labeler

- Type the DUNS Number for the labeler code owner's headquarters.
- Ensure **no hyphens** are included in the DUNS Number.
- Do not include spaces (created w/space bar) before or after DUNS Number
- Ensure that the labeler DUNS Number is the same as the number in the NDC Labeler Code SPL which has the labeler code which is the first segment of the NDC in this listing SPL.


Registrant Listing for PLD Name

| Registrant | |
|------------|-------------------|
| Name | API Manufacturers |

- The registrant (owner/operator) of establishments which manufactured the bulk ingredient product) name is included **IF** the registrant is listing a drug made for a private label distributor.
- Otherwise, **DO NOT** complete this field in the listing SPL.
- Use the business name of registrant.

Registrant Listing for PLD DUNS Number

| Registrant | |
|-------------|-------------------|
| Name | API Manufacturers |
| DUNS number | 885921029 |




Enter DUNS Number for registrant

- Type the DUNS Number for the registrant.
- **Only complete this field if you are the registrant listing on behalf of the PLD.**
- Ensure no hyphens are included in the DUNS Number.
- Do not include spaces (created w/space bar) before or after DUNS Number

Marking the Registrant As Confidential

| Registrant | |
|----------------------|--------------------------|
| Name | API Manufacturers |
| DUNS number | 885921029 |
| Mark as Confidential | <input type="checkbox"/> |



Check the box if the registrant is confidential

- Use checkbox if the registrant information is confidential.
- Information marked confidential will be redacted by FDA system prior to publication of data should information in this file be made public.


Adding Establishments to Listing File

| Establishment | |
|---------------|-------------------|
| Name | API Manufacturers |

- The establishments are the entities involved in the manufacturing or processing the drug product. Enter one or more establishments.

Entering DUNS Number for Establishment

| Establishment | |
|---------------|-------------------|
| Name | API Manufacturers |
| DUNS number | 885921029 |




Enter DUNS Number for Establishment

- Type the DUNS Number for the establishment.
- Ensure **no hyphens** are included in the DUNS Number.
- Do not include spaces (created w/keyboard space bar) before or after DUNS Number

Marking Establishment As Confidential

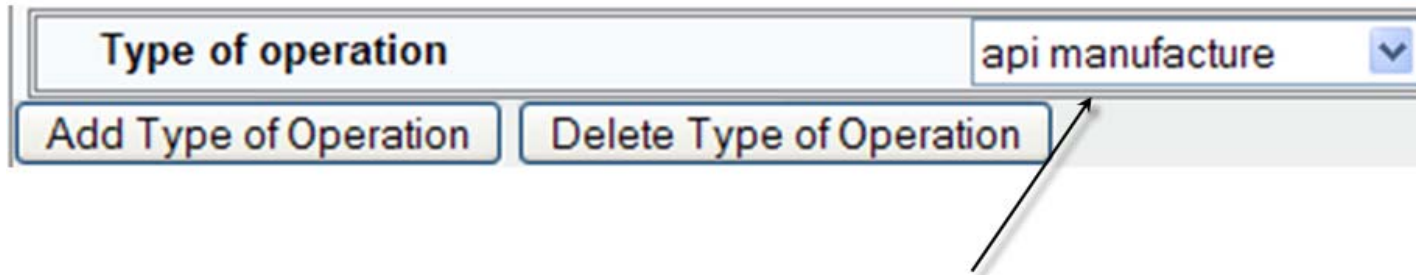
| Establishment | |
|----------------------|--------------------------|
| Name | API Manufacturers |
| DUNS number | 885921029 |
| Mark as Confidential | <input type="checkbox"/> |



Check the box if the establishment information is confidential

- Check if the establishment information is confidential.
- Information marked confidential will be redacted by FDA system prior to publication of data should information in this file be made public.

Type of Operation for Establishment



The screenshot shows a web interface for managing operations. At the top is a header bar with the text 'Type of operation' on the left and a dropdown menu on the right displaying 'api manufacture'. Below this header are two buttons: 'Add Type of Operation' and 'Delete Type of Operation'. An arrow points from the text 'Use drop-down list to select appropriate type of operation' to the dropdown menu.

Use drop-down list to select appropriate type of operation

- Select a type(s) of operation performed at the establishment for this specific drug product.
- Click the “Add Type of Operation” button to add **additional** operations. If no additional operations, ignore this button.
- For APIs, the type of operation: “**api manufacture**”.

Additional Establishments



- To include additional drug establishments, click the “Add Establishment” button.
- To remove drug establishments, select “Delete Establishment”.

Add Product Data Elements Section



- Each bulk ingredient listing SPL should have at least one product data elements section.
- Click the “Add Product” button

Product Data Elements Section ID

| | |
|----|--------------------------------------|
| ID | e9612806-2469-4113-b5d2-dca534e4e145 |
|----|--------------------------------------|



Add an ID for product data element section


- Each section has an ID (GUID)
- Add the ID for product data element section.

Section's Effective Time (Date)

| | |
|----------------|----------|
| Effective Time | 20090626 |
|----------------|----------|

- Enter a time stamp (effective time) for the section
- Ensure that there are no spaces (created w/space bar) before or after date.
- The effective time provides a date reference for the section.
- The date includes the year, month and day using the format `yyyymmdd`.

Dosage Form

| Product Information | |
|---------------------|--|
| Dosage Form | POWDER  |

- The dosage form of the drug product is the physical form as packaged.
- Select the appropriate dosage form from the drop down list.
- For APIs, the dosage form is either “**powder**” or “**liquid**”

Proprietary Name

Proprietary Name

Topiramate

- The proprietary name is the brand or trade name **without additional qualifiers** such as “extra strength” or “XR”.
- For drug products **which do not have a proprietary name, include the non proprietary name without additional qualifiers as the proprietary name.**
- Enter the proprietary name. If there is a suffix, leave a space after the name.

Proprietary Name Suffix

Proprietary Name Suffix

- The proprietary name suffix is **the additional qualifiers** added to the proprietary name.
- If there are no additional qualifiers, then leave suffix field empty.
- **DO NOT** include “USP” in the proprietary name or proprietary name suffix fields in the product data elements.

Non-proprietary Name

Non-Proprietary Name

Topiramate

- Enter name(s) of active ingredient(s) in the non-proprietary name field in product data elements section.
- **DO NOT** include “USP” in the non-proprietary field in the product data elements section

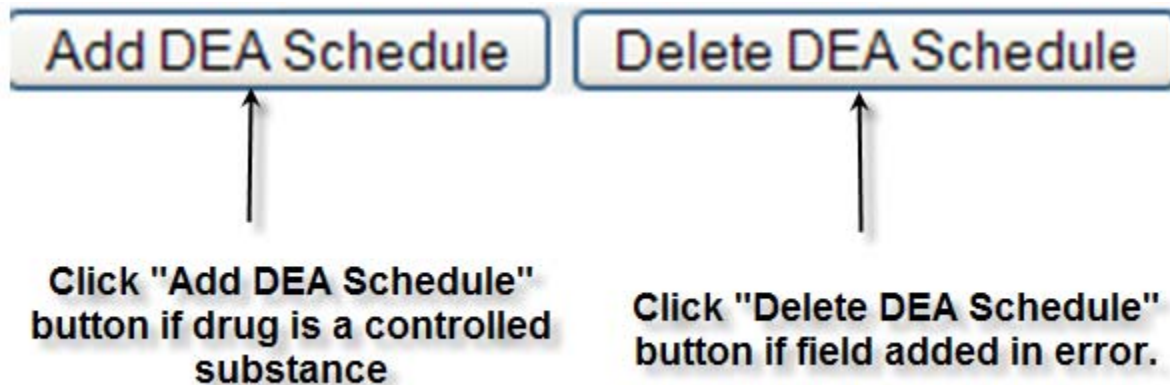
NDC Product Code

NDC Product Code

11445-123

- The NDC Product Code is the NDC Labeler Code and the product segment of the NDC separated by a hyphen.
- Enter the NDC Product Code

DEA Schedule



- Click “Add DEA Schedule” button, if applicable.
- From the drop-down menu, select the appropriate DEA schedule for the drug product

Route of Administration

| | | |
|-------------------------|----------------|---|
| Route of Administration | NOT APPLICABLE | ▼ |
|-------------------------|----------------|---|

- Click “Add Route of Administration” button
- Select the route of administration applicable for the bulk ingredient.
- “**Not Applicable**” is the only acceptable route of administration term for a bulk ingredient in a listing SPL.

Active Ingredients



- Click “Add Active Ingredient” button if there are active ingredients. (There should be an active ingredient in an API listing SPL document.)
- Select “Delete Active Ingredient” button if chosen in error.
- Select “Add Active Ingredient” button for each active ingredient.

Active Ingredient Name

Active Ingredient


Name

Topiramate

- Enter active ingredient name (preferred name) without additional qualifiers such as “USP,” “NF,” etc...

Adding UNII for Active Ingredient

| Active Ingredient | |
|-------------------------------------|------------|
| Name | Topiramate |
| Unique Ingredient Identifier (UNII) | 0H73WJJ391 |



Enter UNII for active ingredient

- Enter the preferred name and Unique Ingredient Identifier (UNII) for the active ingredient.
- Select UNII from list accessible via this web page:
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162523.htm>
- If UNII is not in list, request UNII via e-mail to spl@fda.hhs.gov.

Strength of Active Ingredient

| Active Ingredient | | | |
|-------------------------------------|------------|----|---------|
| Name | Topiramate | | |
| Unique Ingredient Identifier (UNII) | 0H73WJJ391 | | |
| Strength | 1 | kg | in 1 kg |

Express strength as a ratio.
Use metric units

- Strength is represented as a ratio.
- The numerator and denominator have a value and a unit.
- The value is the amount of ingredient for a dose (usually a whole number) based on either the active ingredient or active moiety.
- Enter the value and select the appropriate unit for the numerator and denominator for the strength.
- For **bulk ingredients**, the unit of measure in the numerator and denominator are identical (e.g. 1 kg in 1 kg)

Active Moiety Name

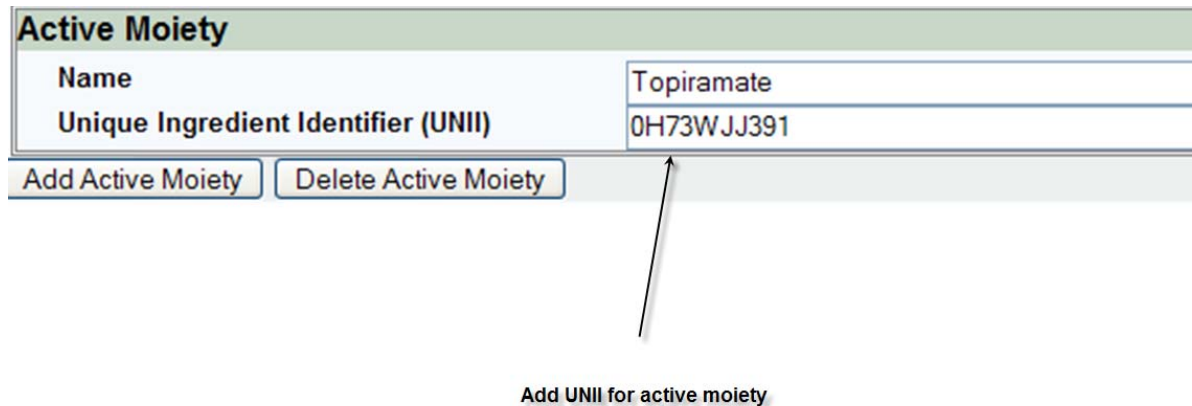
Active Moiety

Name

Topiramate

- There are one or more active moieties for each active ingredient.

Entering UNII for Active Moiety



The screenshot shows a web form titled "Active Moiety". It contains two input fields: "Name" with the value "Topiramate" and "Unique Ingredient Identifier (UNII)" with the value "0H73WJJ391". Below these fields are two buttons: "Add Active Moiety" and "Delete Active Moiety". An arrow points from the text "Add UNII for active moiety" below the form to the UNII input field.


| Active Moiety | |
|-------------------------------------|------------|
| Name | Topiramate |
| Unique Ingredient Identifier (UNII) | 0H73WJJ391 |

Add UNII for active moiety

- Enter the preferred name and UNII for the active moiety for the active ingredient.
- Select UNII from list accessible via this web page:
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162523.htm>
- If UNII is not in list, request UNII via e-mail to spl@fda.hhs.gov.
- Click “Add Active Moiety” button to include additional active moieties.


Basis of Strength

Basis of Strength

Active Ingredient 


- Select if the active ingredient or active moiety was used as the basis of the strength of the drug.

Marketing Status of Product

| Marketing Date | |
|----------------|--|
| Product Status | Active  |

- The marketing status describes the activity of the product.
- If the product is on the market, choose “Active.”
- If the product is no longer on the market, choose “Completed” as the marketing status.

Entering Marketing Start Date for Product

| Marketing Date | |
|----------------------|--|
| Product Status | Active  |
| Start Marketing Date | 20080313 |

- If product is on the market, enter the approximate start marketing date using the YYYYMMDD format.

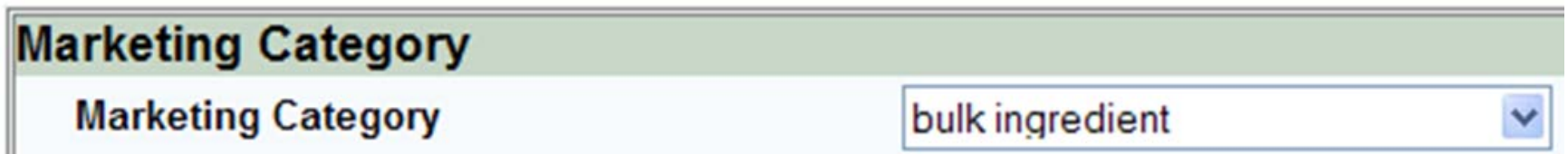
Entering Marketing End Date for a Discontinued Product

| Marketing Date | |
|----------------------|-----------|
| Product Status | Completed |
| Start Marketing Date | 19830313 |
| End Marketing Date | 20091003 |

Enter approximate end marketing date if delisting the product

- If marketing of product is discontinued, select “Completed” from the Product Status drop-down menu.
- Then enter the approximate end marketing date using the YYYYMMDD format in the “End Marketing Date” field.

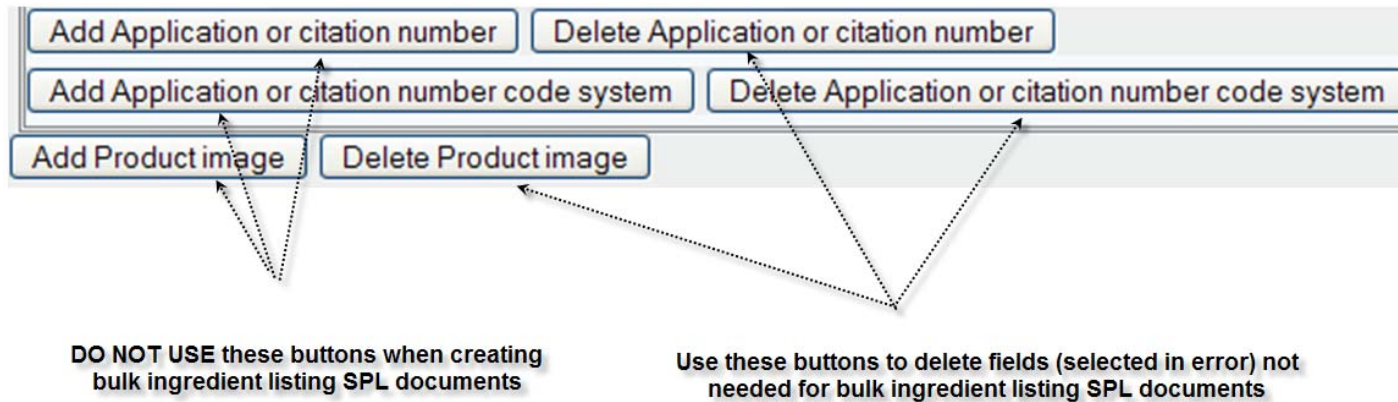
Marketing Category



The image shows a web form with a title bar that reads "Marketing Category". Below the title bar, there is a label "Marketing Category" followed by a dropdown menu. The dropdown menu currently displays the text "bulk ingredient" and has a small blue downward-pointing arrow icon on its right side.

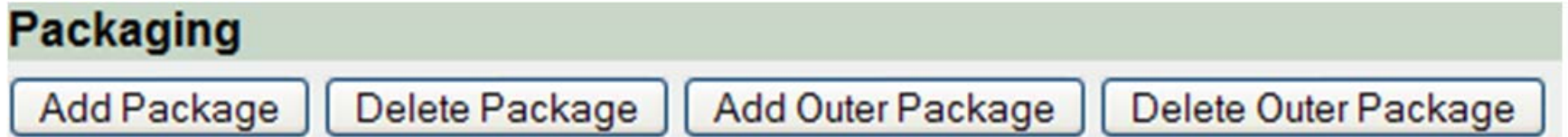
- Select the marketing category for a bulk ingredient from the drop-down menu.
- The marketing category should be “**bulk ingredient.**”

Application, Code System, & Product Image Buttons



- For **BULK INGREDIENT** listing SPL documents:
 - **DO NOT** add an application or regulatory citation number unless one exists for your product.
 - **DO NOT** add an application or citation number code system
 - **DO NOT** use add a product image.

Packaging



- Click on the “Add Package” button to add a new package configuration.

Entering NDC Package Code

The diagram illustrates the structure of the NDC Package Code. It features a header bar labeled "Packaging" in a green box. Below it is a form field labeled "NDC Package Code (10 digit)" containing the text "11145-123-01". A vertical dashed arrow points from the first five digits "11145" to a text box stating: "NDC Labeler Code (1st segment) in this file should match the labeler code in the NDC Labeler Code SPL file." A diagonal dashed arrow points from the last two digits "01" to another text box stating: "NDC Product Code (1st two segments should match NDC Product Code entered earlier in this file." The middle segment "123" is not pointed to by any arrow.

- Enter the 10 character NDC Package Code. The NDC Package Code is the NDC Product Code and the package segment of the NDC separated by a hyphen.
- NDC Labeler Code (1st segment) should match labeler code in the NDC Labeler Code SPL file.
- NDC Product Code (1st two segments) should match the NDC Product Code entered in the NDC Product Code field of same file.
- **DO NOT** use asterisks in package code field.

Entering Quantity for Packaging Description

| | | | |
|----------|----|----------|---|
| Quantity | 25 | KILOGRAM | ▼ |
|----------|----|----------|---|

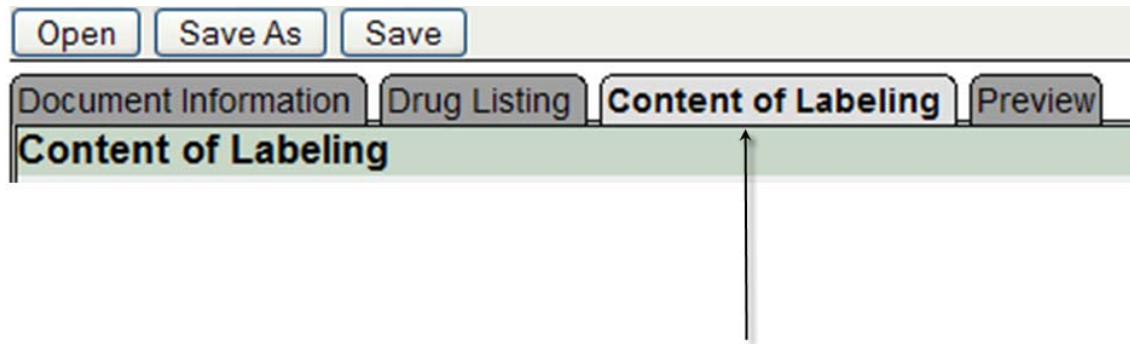
- Enter the quantity in the first field and then select the appropriate unit.
- The unit is the same as the denominator unit for the ingredient strength.
- The UCUM will be used in the strength description. Example:
strength: “kg” & term will be used in **package description:** “KILOGRAM.”
- If bulk ingredient is sold “**as ordered**,” enter in the quantity field the largest amount of product sold in the container associated with this NDC.

Adding Package Type

| | | |
|--------------|------|---|
| Package Type | DRUM | ▼ |
|--------------|------|---|

- Select the appropriate package type for a bulk drug substance container.

Content of Labeling for Bulk Ingredient Listing SPL Document



Click the "Content of Labeling" tab to navigate to the content of labeling section of listing SPL Xforms

- Click the “Content of Labeling” tab to navigate to the content of labeling view of SPL Xforms.

Adding SPL Document Title for **Bulk Ingredient** Listing SPL Document



- Click on the “Add title” button.
- Enter the title of the label. If there is no title, remove title field, if necessary.

Add Section



Add at least one content of labeling section

- Click the “Add Section” to add the section.

Choose Section Header

| | | |
|---------|---------------------------------------|---|
| Section | PACKAGE LABEL.PRINCIPAL DISPLAY PANEL | ▼ |
|---------|---------------------------------------|---|

- Choose a section header from drop-down menu.
- **Bulk ingredient** listing SPL should have a “Package Label.Principal Display Panel” section header.

Hyperlink ID



- **IGNORE** “Hyperlink” buttons for bulk ingredient SPL listing documents.

Enter Section ID

ID

62675ee0-e6f7-4488-8947-39e1d57fbb04

- Enter a GUID for the section ID.

Adding Section Title



- Enter a section title, if necessary.
- If no section title, do not click “Add Title.”
- Use “Delete Title” if “Add Title” is selected in error.

Section's Effective Time (Date)

| | |
|----------------|----------|
| Effective Time | 20090626 |
|----------------|----------|

- Enter a time stamp (effective time) for the content of labeling section
- Ensure that there are no spaces (created w/space bar) before or after date.
- The effective time provides a date reference for the section.
- The date includes the year, month and day using the format `yyyymmdd`.

Highlights Feature



- **IGNORE** the highlights buttons for bulk ingredient listing SPL documents.

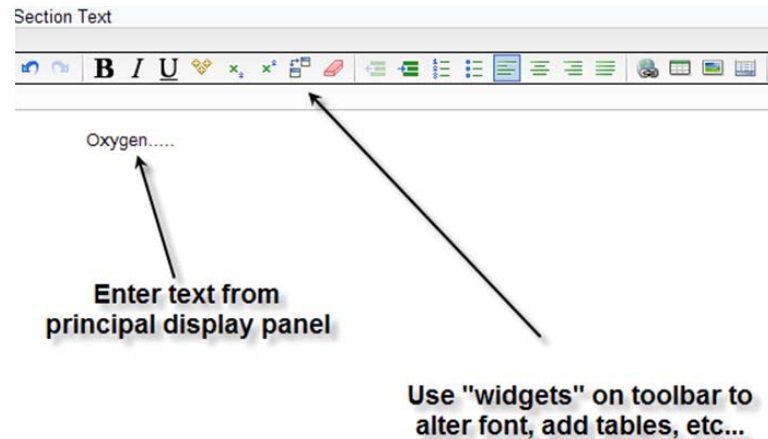
Entering Section Text



Select "Edit" button to
display section text field.

- Click the “Edit” button to display the section text field.

Entering Text and Using “Widgets”



- Enter text from principal display panel of carton/container label.
- Type or copy/paste text into section field.
- Use “widgets” to alter the font (bold, italics), etc...

Saving the Section



- Click the “Save” button to save the section text just entered.

Referencing the Images Using “Add Media” Button

Content of Labeling

Add Title Delete Title

Section PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Add Hyperlink ID Delete Hyperlink ID

ID 276c2bdb-411e-4373-9766-dae2da1a0c5a

Add Title Delete Title

Add Effective time Delete Effective time

Add Highlight Delete Highlight

Section Text
Place holder text

Edit

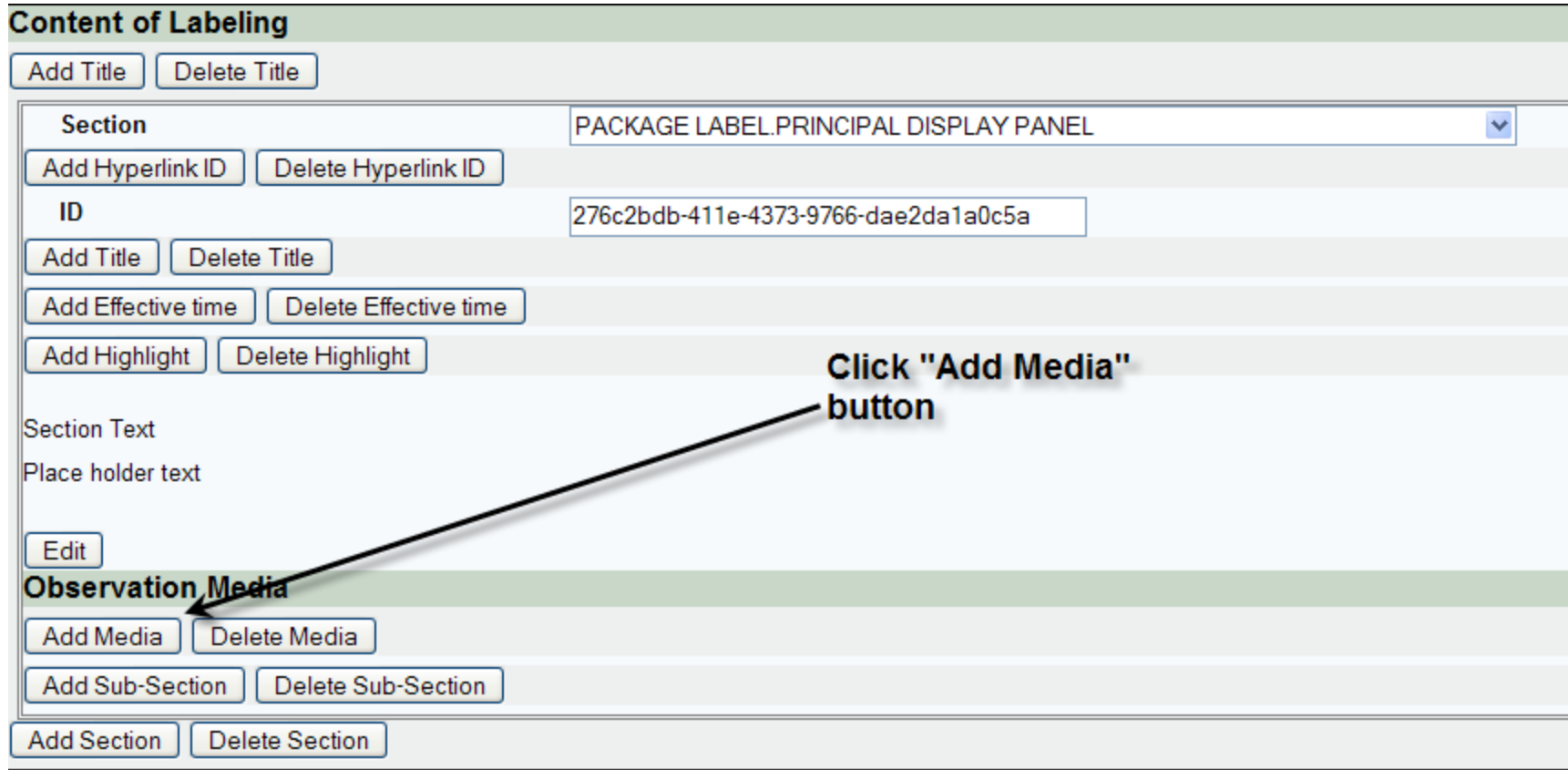
Observation Media

Add Media Delete Media

Add Sub-Section Delete Sub-Section

Add Section Delete Section

Click "Add Media" button



Entering ID, Descriptive Text & File Name

1. Enter an ID (e.g. "MM1" or "MM2" - each image ID should be unique)
2. Add descriptive text for image
3. Enter image file name

Section Text

Place holder text

Edit

Observation Media

| | |
|------------------|-----------------------|
| ID | MM1 |
| Descriptive Text | image of carton label |
| File Name | carton.jpg |

Selecting Location of Image

Section Text

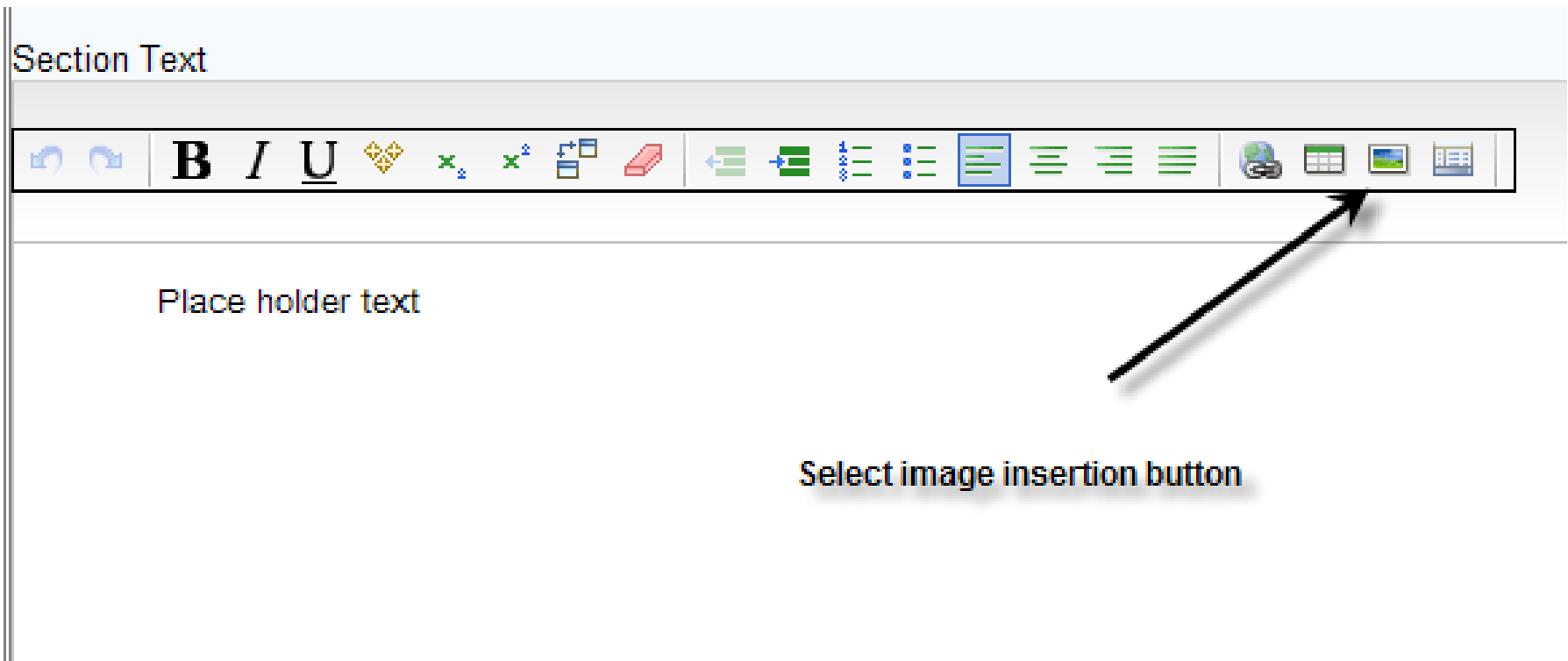


Place holder text

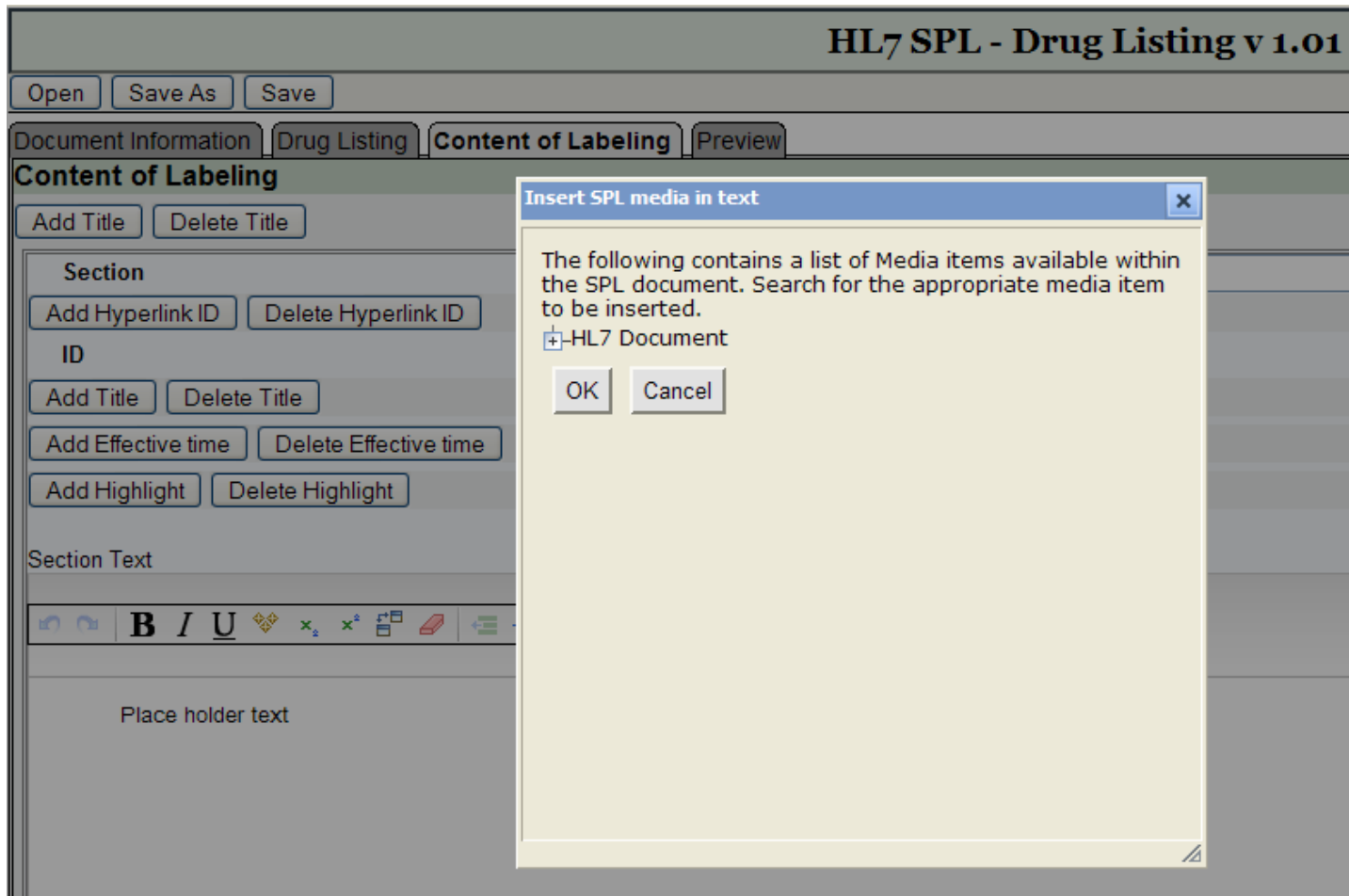


Place the computer cursor in the location where image should appear

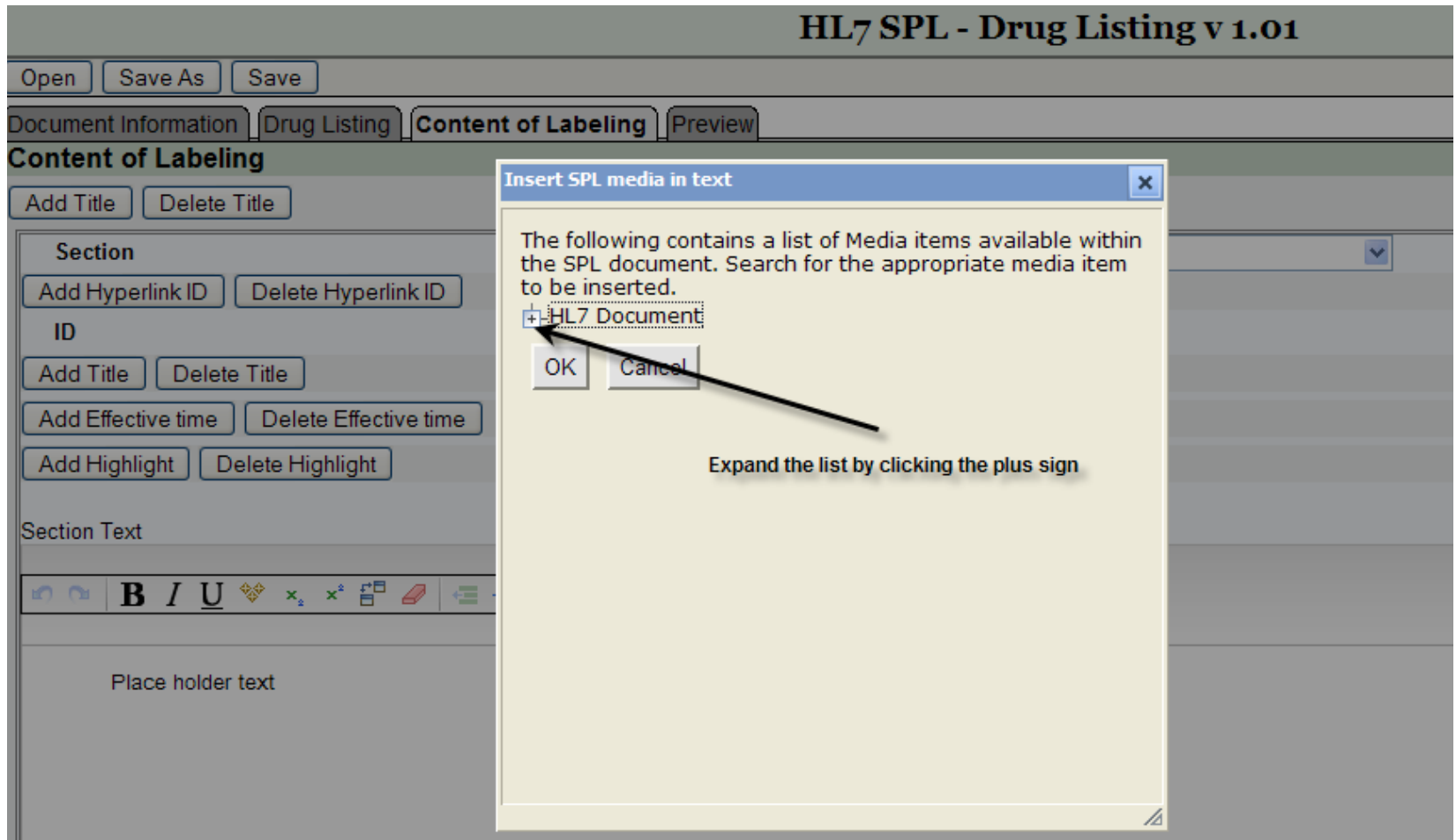
Selecting Image Insertion Button



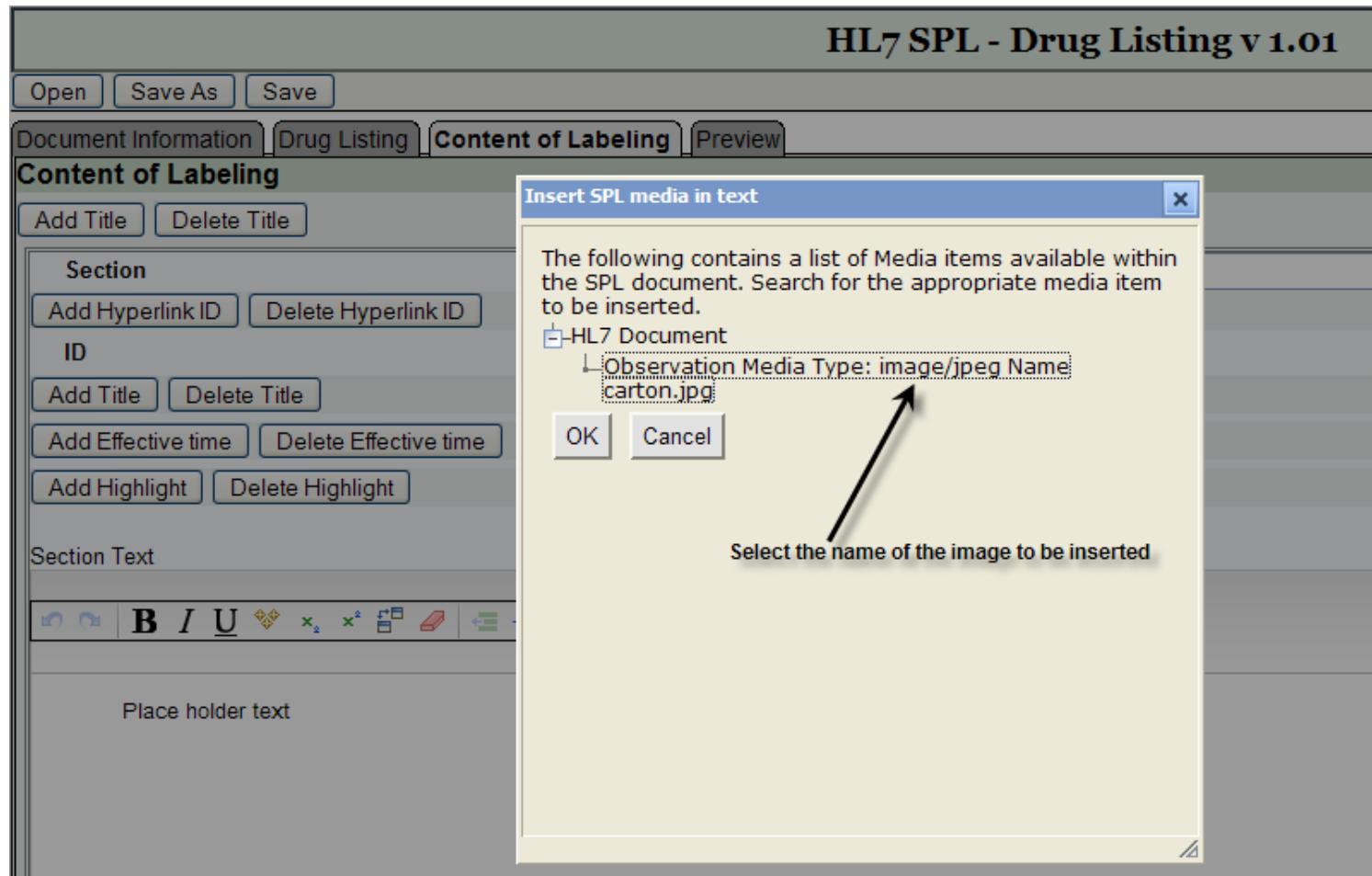
Insert Media Prompt Box



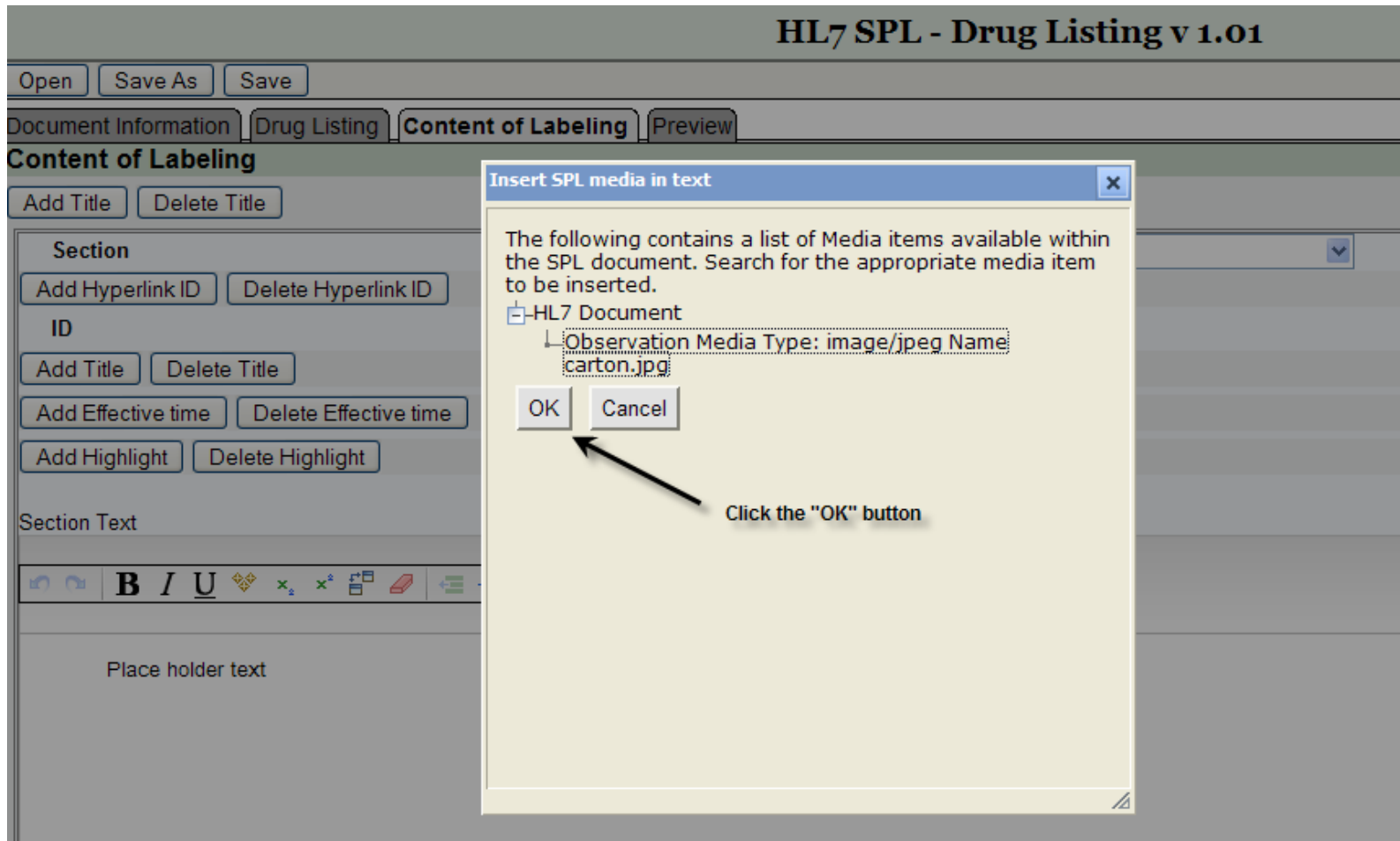
Expanding Image List



Selecting Image to Insert



Finish Image Selection



Verifying Image Insertion

Section Text



Place holder text



An image placeholder icon will appear (image will not render in SPL Xforms)

Saving Section w/Image

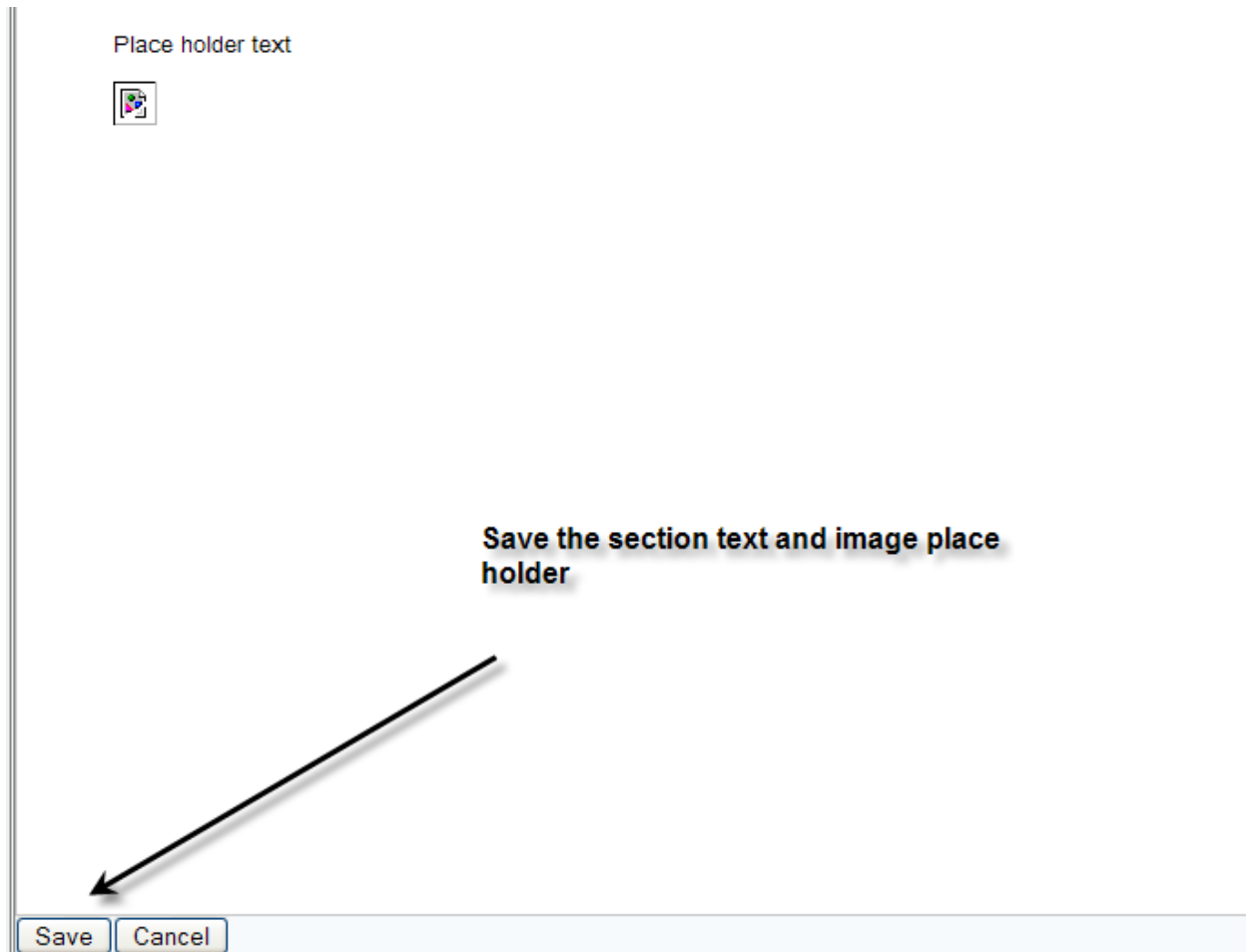
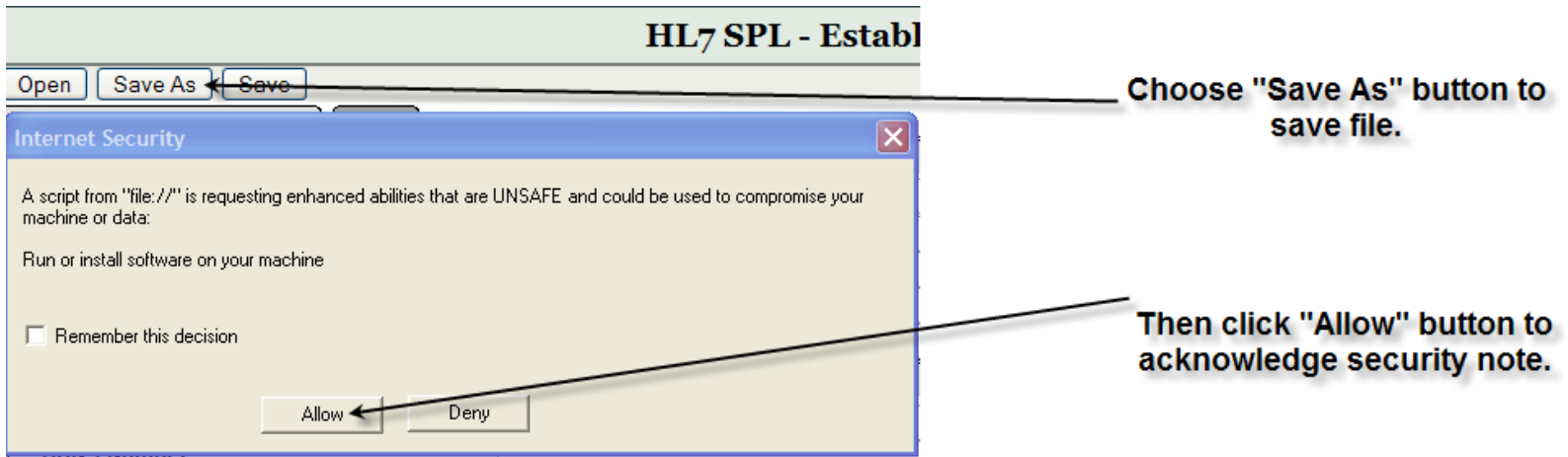


Image Notes

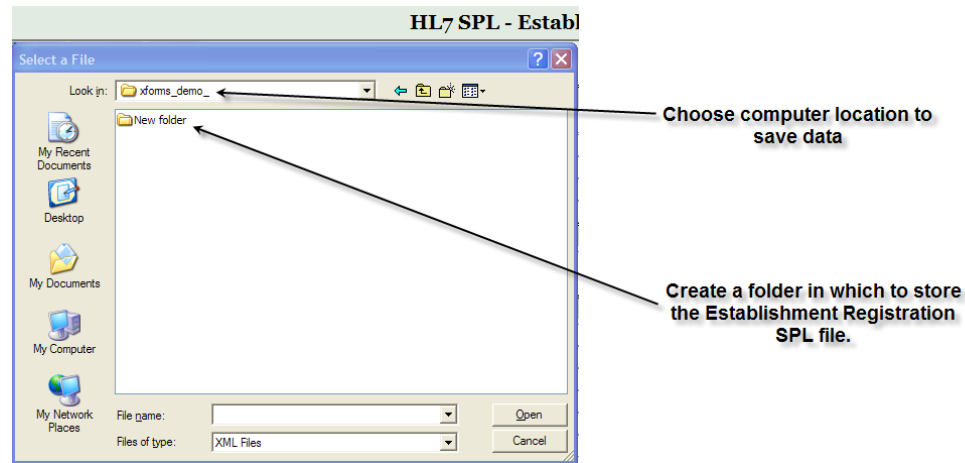
- Image should be viewable in window without scrolling.
- Size of image file should be under **1 MB**.

Saving the File



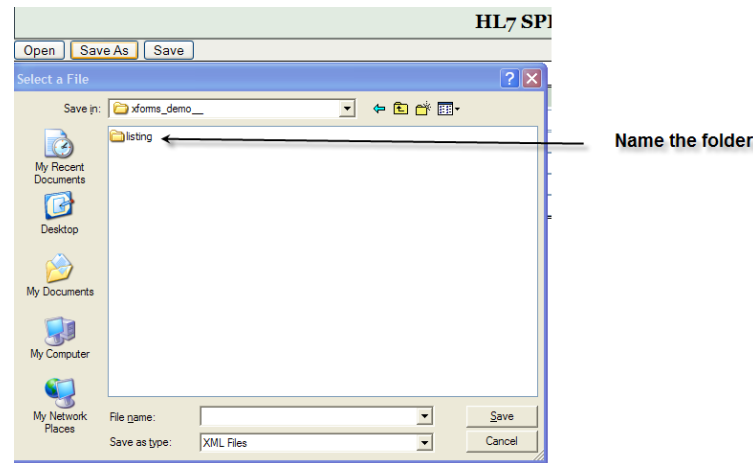
- When saving the SPL file for the first time, select the “Save As” button.
- Then select the “Allow” button to continue saving.
- You can check “Remember This Decision” checkbox to avoid future security prompts.

Creating the Submission Folder



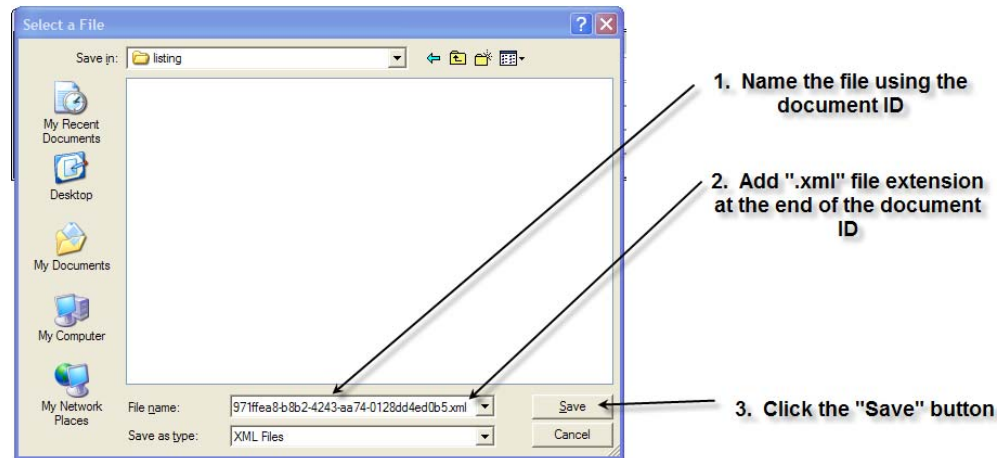
- Choose computer location in which to store folder to contain the SPL file.
- Create a folder in which to store the listing SPL file.

Naming the Submission Folder



- There is no folder naming convention
- However, we recommend that you not use symbols in the name of the folder.

Naming the SPL File



- Use the **document ID** (GUID) as the document file name
- Use “.xml” as the file extension
- Choose “Save” button
- If you do not follow these steps your SPL will **FAIL** validation.

Listing a API w/Finished Dosage Form Product

- Instead of listing API in a separate SPL document, you can also list API w/finished dosage form product's listing SPL.
- Inclusion of the establishment which manufactured the API in the SPL file for the finished dosage form product electronically lists the API.

Need More Detailed Instructions?

- Use Step-by-Step Instructions for Creating Structured Product Labeling (SPL) Files for Drug Establishment Registration and Drug Listing
- This document is located on the SPL Resources web page:
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

Test Your SPL R4 Submissions

- Use Pragmatic Data Validator Lite to test your SPL files prior to transmission to FDA:
<http://www.fda.gov/ForIndustry/DataStandards/ucm155514.htm>
- NOTE
 - This validator tool is **NOT** connected to FDA database.
 - This tool assist you in detection of 90 – 95% of technical errors in SPL documents.

Submitting Files via FDA Gateway

WebTrader Help Logout

Send document

Select who will receive the document

Gateway: FDATST

Center: **Select the "OC" center**

Select the contents of the submission

Enter a path to a file or a directory. If a directory is entered, then the entire contents of the directory will be included in the submission. All the paths stored in the submission will be relative from the provided directory path unless an alternate root directory is entered.

Path: **Browse...** **Ensure that you are submitting SPL in a folder (file name should not appear in the path field)**

Root directory: **Browse...**

Submission type: **Select "SPL" as the submission type**

Select a signing certificate

Current file: M:\SPL_Main\gateway\Lonnie Smith\Lonnie Smith.p12

New file: **Browse...**
MyCertificate.p12 or MyPrivateKey.pfx

Send

Stay Informed

- Join FDA Data Standards Council listserv
- <http://www.fda.gov/ForIndustry/DataStandards/default.htm>



The screenshot shows the FDA Data Standards Council website. At the top is the U.S. Department of Health & Human Services header with the www.hhs.gov URL. Below is the FDA U.S. Food and Drug Administration logo and a search bar. A navigation bar lists various FDA categories. The 'For Industry' section is highlighted, with a breadcrumb trail: Home > For Industry > Data Standards. On the left is a 'Data Standards' sidebar menu with links to Validators, Data Council, Structured Product Labeling, Individual Case Safety Reports, and Regulated Product Submission. The main content area is titled 'FDA Resources for Standards' and features a 'Sign up for email updates.' link with an arrow pointing to it. Below this is a paragraph about the council's role and a link to 'Structured Product Labeling'.

U.S. Department of Health & Human Services www.hhs.gov

FDA U.S. Food and Drug Administration

A-Z Index Search go

Home | Food | Drugs | Medical Devices | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Radiation-Emitting Products | Tobacco Products

For Industry Email this page Print this page Change Font Size

Home > For Industry > Data Standards

Data Standards

- Validators
- Data Council
- Structured Product Labeling
- Individual Case Safety Reports
- Regulated Product Submission

FDA Resources for Standards

 Sign up for email updates. ←

The FDA Data Standards Council coordinates the evaluation, development, maintenance, and adoption of health and regulatory data standards to ensure that common data standards are used throughout the agency.

[Structured Product Labeling](#)

SPL-related Technical Assistance/Questions

- SPL e-mail account (spl@fda.hhs.gov)